REMARKS/ARGUMENTS

Request For Continued Examination

Herewith, Applicants submits a Request for Continued Examination to further prosecution. Entry of the RCE and substantive examination is respectfully requested.

Status of the Claims

Claims 92-95, 104-121 are currently pending. By the present amendment, claim 93 is canceled. Claims 92, 94, and 95 are amended. Thus, claims 92, 94-95 and 104-121 are currently under examination. No new matter has been added with these amendments.

Interview Summary

On October 23, 2007, Applicant's attorney and named inventor Dr. Bernhard Kaltenboeck conducted an interview with Examiner Vanessa Ford and Examiner Nita Minnifield. The interview was made in response to a statement in the Advisory Action of September 19, 2007 wherein the Examiner requested that "[i]n an effort to expedite prosecution in this application, the Office requests that Applicant contact the Examiner to schedule an in-person or telephonic interview to explain the essence of the invention, explain the experimental data presented in the instant specification when the invention was applied for and answer any other questions related to the claimed invention." During the interview, the claims were discussed and in particular, claim 92 was discussed.

During the interview Dr. Kaltenboeck and Applicant's Attorney answered clarifying questions from the Examiners as to how the sequence ID numbers (SEQ. ID) relate to the findings as demonstrated in the figures, tables, and examples of the original application. As an aid, a chart was provided to demonstrate, with complete specificity, how particular protective *C. psittaci* gene fragment numbers in Figure 5 correlate to the CP4 (*C. psittaci* round 4) designation in Figure 6 and Table 2. The chart also demonstrates how one CP number is correlates to two separate Sequence ID numbers. One CP4# actually correlates to 4 separate Seq. ID numbers - an original DNA gene fragment sequence number, a polypeptide fragment sequence number, a full length DNA gene sequence number and a full length polypeptide sequence number. The polypeptide fragment sequence number is the amino acid sequence designated by the original DNA gene fragment, while the full length polypeptide number is the amino acid sequence designated by the full length DNA gene sequence number. Moreover, the *fragment* numbers are **a subset** of the *full-length* sequences, e.g. SEQ. ID. NO:9 is the *full length* amino acid sequence, while SEQ. ID. NO:7 is the *fragment* amino acid sequence. The chart is submitted as Exhibit 1 to the present Amendment.

In response to the Examiners' inquires, Dr. Kaltenboeck explained the experimental strategy that led to the identification of plasmids containing the protective *C. psittaci* genes. Briefly, Dr. Kaltenboeck explained:

- a shotgun library of the *C. psittaci* genome in an eukaryotic expression plasmid was prepared, mice were DNA-vaccinated with pools of these plasmids, challenged with *C. psittaci*, and scored for protection - the overall approach of expression library immunization (ELI) is schematically explained in Example 1 (pp. 65-67) as well as in Figs. 1 and 2 (p. 14);
- pools of protective plasmids were selected for subsequent rounds of DNA vaccination and challenge in the process of deconvoluting the library into single plasmids containing inserts of protective *C. psittaci* genes-this deconvolution process is described in Example 1, chapter 3 (p. 66);
- the materials and methods used in rounds 1-3 of the *C. psittaci* library deconvolution are described in Example 2 (p. 67-70) and Fig. 3 (p. 14);
- vaccination of mice and their *C. psittaci* challenge are detailed in Example 3 (p. 70);
- results of rounds 1-3 of the deconvolution process are described in Example 4 (p. 71) and in Fig. 4 (p. 14);
- the inserts of all plasmids of the protective groups identified in round 3 were sequenced, and inserts with open reading frames of more than 150 nucleotides (50 amino acids) were considered correct open *C. psittaci* open reading frames because if they had been random sequences in the wrong reading frame, a termination codon would have most likely occurred earlier;
- 14 plasmids were identified and then were tested against a control in *C. psittaci* round 4 (CP4) as individual plasmids # 1-14, and as pool of all 14 plasmids > 50 amino acids - the results of the protection scores in round 4 indicating vaccine efficacy are shown in Fig. 5 (p. 15);
- the sequences of the 14 plasmids inserts were analyzed, the full *C. psittaci* genes isolated, the position of the fragments within the full genes determined, and the full genes characterized for gene terminology and function by homology search - these results and shown in Fig 6 (p. 15), described in Example 6 with a summary

in Table 2 (p. 74) and a complete listing of all sequences with SEQ ID NOs in Table 3 (p. 75-80).

Dr. Kaltenboeck explained that the results of this experiment represent the claimed subject matter of the present application. Specifically, identification of the protective *C. psittaci* sequence inserts noted in Fig. 5 would undoubtedly convey to one of ordinary skill in the art the following: a) proper translation of the identified nucleotide sequence into a corresponding polypeptide that is the actually protective principle in DNA vaccination; b) use of such a corresponding polypeptide (produced by any of various standard methods) for protective vaccination by standard methods for vaccination known to anyone knowledgeable in the art; c) determination of the full-length nucleotide sequence of the gene and its putative function; and d) use of the corresponding full-length polypeptide (produced by any of various standard methods) for protective vaccination by standard methods for vaccination known in the art.

Dr. Kaltenboeck also provided details about a separate experiment for vaccination of cattle, described in application Example 9 (p. 83) and Table 4 (p. 84). This experiment was designed to confer maximum protection and therefore used the pool of the 5 best protective *C. psittaci* genes either as full-length genes used in a DNA vaccine, or as the protein vaccine, using a standard protein vaccine preparation. Dr. Kaltenboeck noted that Fig. 5 and the associated experiments demonstrate that vaccination with the pool of

protective plasmids (containing the fragment nucleotide sequences) mediates higher protection in mice than vaccination with any individual plasmid (Fig. 5, see pool (> 50 AA) versus plasmids 1-14; legend p. 15). Accordingly, in Experiment 9, heifers were vaccinated with either vaccine and subjected to herd challenge with *C. psittaci*. This challenge significantly reduced fertility in the heifers vaccinated with a control vaccine, but not in the heifers vaccinated with DNA or protein vaccine containing the *C. psittaci* genes. As noted by Dr. Kaltenboeck, the protective efficacy of *C. psittaci* DNA as well as protein vaccines demonstrates that: a) the full length gene sequences containing the fragments identified in Fig. 5 are protective; and b) protection is conferred whether the vaccination is DNA vaccination or a protein vaccination.

Thus, applicants concluded that the claimed subject matter was clearly enabled by the present specification to one of ordinary skill in the art. Applicants respectfully emphasized that anyone knowledgeable in the art understands that DNA vaccination with a nucleotide sequence will also mediate protection conferred by vaccination with the corresponding protein sequence, since the nucleotide sequence is translated intracellularly into the protein sequence before providing a protective response. Applicant's attorney noted that he believed case law exists to this effect. Such case law is set forth, below. Moreover, Applicants reiterated that one of skill in the art will understand that vaccination with a full length sequence will provide the same level of protection as an identified protective fragment in that sequence, since the full length sequence necessarily contains the fragment sequence.

Ultimately, although the Examiners stated that their understanding of the claimed subject matter and application was clarified, no decision on patentability was noted by the Examiners. Applicants accordingly hereby submit the present Request For Continued Examination, Amendment and Remarks.

Substantive Remarks

Applicant hereby incorporates by reference the summary of the interview noted above. By the present amendment, claim 93 is cancelled and claims 92, 94 and 95 are currently amended.

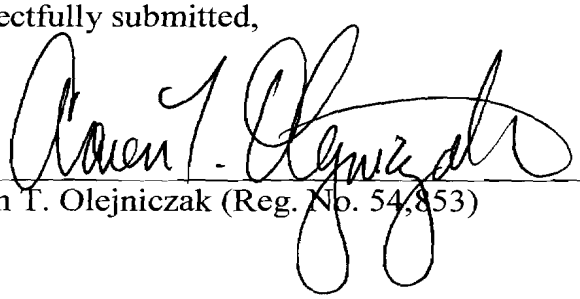
Claim 92 is amended to recite that the antigen comprises SEQ ID No:7. SEQ ID No:7 is the amino acid sequence of most highly protective gene fragment identified in Examples 1-4 and Fig. 5, namely, Fig. 5 round four gene fragment 1, i.e., CP4#1. This claim is clearly enabled because Examples 1-4 and Fig. 5 demonstrate the efficacy of gene fragment in conferring protection and because it is "a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it." In Re Wallach, 378 F.3d 1330, 1334, 71 USPQ 2d (BNA) 1939 (Fed. Cir. 2004).

Claims 94 and 95 are amended to recite a combination of SEQ ID NOs that are commensurate in scope with Example 9. As noted, Example 9 demonstrates that that vaccination with a pool of protective genes or protein sequences, whether fragments or full length, mediates even higher protection in mice than vaccination with any individual plasmid.

Applicant respectfully submits that the above-noted amendment in conjunction with the through expiation provided by Dr. Kaltenboeck in his declarations as well as in the interview of October 23, 2007 is overly sufficient to move the present case to allowance. Such action is earnestly solicited.

As always, Applicant invites the Examiner to contact the undersigned to discuss and matters that might help further more the case to issuance.

Respectfully submitted,



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